Remarks

This Amendment is responsive to the Office Action mailed March 27, 2002 (Paper No. 20). Entry of this Amendment and reconsideration of the subject application in view thereof are respectfully requested.

Claims

Claims 1-24 and 26-36 were pending. Claims 1-24 and 26-36 stand or stood rejected.

Claims 2, 6 and 24 have been cancelled without prejudice or disclaimer of the subject matter contained therein.

New claims 37-39 have been added and claims 1, 7, 8, 10, 17, 21 and 26-27 have been amended to more particularly and distinctly define the invention. No new matter is added.

Support

Support for new claims 37-39 and for the amendments to claims 1, 7, 8, 10, 17, 21 and 26-27 is apparent. No new matter has been added.

Claim Rejections under 35 U.S.C. § 102

Claims 1-8, 13, 18-24, 27 and 36 stand or stood rejected under 35 U.S.C. § 102 as anticipated by U.S. Patent No. 6,007,836 ('836). Specifically, the Examiner asserts that

> '836 discloses transdermal vasodilator systems for producing and maintaining the erection of a male penis comprising a combination of vasodilators such as prostaglandin E1, papaverine, phentolamine and polymer films (abstract; C7, L38-C8, L5; C8, L53-C9, L6). '836 also discloses the inclusion of isopropyl myristate and polyethylene glycol (C8, L41-52). The compositions of '836 produce an erection "on demand, immediately before sexual intercourse" and are therefore thought to be released in less than one hour.
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> Applicant argues that the instant claims are allowable over '836 since '836 requires an adhesive, while the instant claims do not encompass devices having an adhesive. However, this argument is not persuasive since the claims recite comprising as the transitional phrase. Therefore, the claims are still not closed as the claims "further comprise" ingredients including a stabilizer, a

> solubilizer, an enhancer, and a plasticizer. Adhesives fall within these ingredients. Furthermore, one would look to the specification to understand what the disk of the instant claims is. There, one finds that the specification discloses that the disk comprises adhesives.

Without conceding the validity of this rejection, Applicant has elected to present the invention in different terms, which terms should obviate the asserted basis for this rejection. Reconsideration and withdrawal of this rejection are respectfully requested.

Claim Rejections under 35 U.S.C. § 103

Claims 1-8, 10-11, 13, 17-24, 26-27, 29 and 34-36 stand or stood rejected under 35 U.S.C. § 103 as unpatentable over U.S. Patent No. 6,007,836 ('836). Specifically, the Examiner asserts that

> '836 teaches transdermal vasodilator systems for producing and maintaining the erection of a male penis comprising a combination of vasodilators such as prostaglandin E1, papaverine, phentolamine and polymer films (abstract; C7, L38-C8, L5; C8, L53-C9, L6). '836 also discloses the inclusion of isopropyl myristate and polyethylene glycol (C8, L41-52). '836 does not teach the amount of polyethylene glycol to include in the composition. However, it is submitted that this is a manipulatable parameter that would be obvious to one skilled in the art at the time of the invention to manipulate in an effort to increase or decrease flexibility of the polymer film. The compositions of '836 produce an erection "on demand, immediately before sexual intercourse" and are therefore thought to be released in less than one hour. '836 does not state whether the penile surface requires pre-wetting. It is submitted that since it not say that wetting the surface is require, no pre-wetting is necessary. It is also submitted that pre-wetting the surface would be obvious to one skilled in the art at the time of the invention to aid in adhesion of the patch to the skin, since this would aid in creating a vacuum.

Without conceding the validity of this rejection, Applicant has elected to present the invention in different terms, which terms should obviate the asserted basis for this rejection. Reconsideration and withdrawal of this rejection are respectfully requested.

Claims 1-14, 17-24, 26-30 and 34-36 stand or stood rejected under 35 U.S.C. § 103 as unpatentable over a combination of '836 and U.S. Patent No. 4,969,821 ('821). Specifically, the Examiner asserts that

> '836 is relied upon for all that it teaches as stated previously.
>
> '821 is relied upon for teaching that polyvinylpyrrolidone film is an effective means for controlling the release of an active agent when administered transdermally. '821 also teaches the inclusion of plasticizers in the polyvinylpyrrolidone films wherein the plasticizer is PEG 400. The amount of plasticizer is unclear since '821 teaches weight per volume of liquid. Should applicants traverse on the grounds that the amount of plasticizer of '821 is outside the instant ranges, applicants are requested to submit evidence pertaining thereto. Furthermore, it is submitted that the ranges pertaining to the amount of plasticizer is a manipulatable parameter and it would be obvious to one skilled in the art at the time of the invention to adjust the amount of plasticizer in the composition to increase of decrease the flexibility of the film.
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> Accordingly, it would have been obvious to one skilled in the art at the time of the inveniton to construct the films of the '836 from polyvinylpyrrolidone with the expectation that these films would control the release of drug from the patch and the motivation lying therein.

Without conceding the validity of this rejection, Applicant has elected to present the invention in different terms, which terms should obviate the asserted basis for this rejection. Reconsideration and withdrawal of this rejection are respectfully requested.

Claims 1-8, 10-11, 13, 15-24, 26-27, 29 and 31-36 stand or stood rejected under 35 U.S.C. § 103 as unpatentable over a combination of '836 and FR 2710649. Specifically, the Examiner asserts that

> '836 is relied upon for all that it teaches as stated previously.
>
> '649 is relied upon for teaching transdermal films formulated as a biodegradable patch comprising gliadin gel based on plant prolamines extracted from cereals (wheat) (abstract, p1).
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> Accordingly, it would have been obvious to one skilled in the art at the time of the invention to construct the polymer films of '836 from gliadin with the motivation to provide a transdermal patch to treat impotence that is biodegradable and the expectation that gliadin transdermal patches are biodegradable.
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> Applicant argues that the instant claims are allowable over '836 since '836 requires an adhesive, while the instant claims do

> not encompass devices having an adhesive. However, this argument is not persuasive since the claims recite comprising as the transitional phrase. Therefore, the claims are still not closed as the claims "further comprise" ingredients including a stabilizer, a solubilizer, an enhancer, and a plasticizer. Adhesives fall within these ingredients. Furthermore, one would look to the specification to understand what the disk of the instant claims is. There, one finds that the specification discloses that the disk comprises adhesives.

Without conceding the validity of this rejection, Applicant has elected to present the invention in different terms, which terms should obviate the asserted basis for this rejection. Applicant further points out that the specification discloses two specific embodiments, namely: (a) one embodiment in which the device is flexible and may contain an adhesive exhibiting pressure senstive properties; and (b) one embodiment in which the device is rigid and does not include an adhesive exhibiting pressure senstive properties. Reconsideration and withdrawal of this rejection are respectfully requested.

FEE DEFICIENCY

☒ This Paper is believed timely filed. If an extension of time is deemed required for consideration of this paper, please consider this paper to comprise a petition for such an extension of time; The Commissioner is hereby authorized to charge the fee for any such extension to Deposit Account No. 04-0480.

and/or

☒ If any additional fee is required for consideration of this paper, please charge Account No. 04-0480.

Closing Remarks

Applicant thanks the Examiner for the Office Action and believes this response to be a full and complete response to such Office Action. Accordingly, favorable reconsideration in view of this response and allowance of the pending claims are earnestly solicited.

Respectfully submitted,

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Version with markings to show changes made

1. (Four Times Amended) A delivery device for treatment of erectile dysfunction in a patient, consisting of a rigid disk, wherein the rigid disk is made of a mixture of materials, wherein the mixture of materials [comprises] consists essentially of a filmogenic polymer and an effective dose of a therapeutic agent suitable for treating erectile dysfunction.

7. (Thrice Amended) The delivery device according to claim ~~38~~ 40 [6], wherein the additional therapeutic agent is selected from the group consisting of: prostaglandin, a testosterone, a yohimbine, a pentoxifylline, a trazodone, an apomorphine, a sildenafil, a minoxidil, a misoprostol, a papaverine, a nitroglycerin, a phentolamine, a moxisylyte, a linsidomine, a linear peptide, a cyclic peptide, and a pyridylguanidine compound.

8. (Thrice Amended) The delivery device according to claim ~~37~~ 39 [2], wherein the enhancer is at least one selected from the group consisting of a glycolipid, a non-esterified fatty acid, an aliphatic alcohol, a fatty acid ester of an aliphatic alcohol, a cyclohexanol, a fatty acid ester of glycerol, a glycol, an aliphatic alcohol ether of a glycol, and a surfactant.

10. (Thrice Amended) The delivery device according to claim ~~37~~ 39 [2], wherein the filmogenic material is present in an amount of 5 to 100%, the therapeutic agent is present in an amount of 0.1 to 20% w/w, the enhancer is present in an amount of 0.01 to 15%, and the plasticizer is present in an amount of 1 to 70%, each on a weight basis.

17. (Thrice Amended) The delivery device according to claim ~~37~~ 39 [2], having a plasticizer in an amount less than 30% on a dry weight basis.

21. (Four Times Amended) A method of treating erectile dysfunction, comprising:

selecting a device consisting of a rigid disk, wherein the rigid disk is made of a mixture of materials, wherein the mixture of materials [comprises] consists essentially of a

filmogenic polymer and an effective dose of at least one therapeutic agent suitable for treating erectile dysfunction;

wetting a penile surface; and

placing the device in contact with the wetted penile surface delivering the at least one therapeutic agent to the penile surface over an effective period of time.

26. (Twice Amended) The method according to claim 39 [24], wherein the plasticizer is present in an amount that is less than 30% on a dry weight basis.

27. (Twice Amended) The method according to claim 39 [24], wherein the plasticizer is a polyethylene glycol (PEG).

Rule 1.126 37. A delivery device for treatment of erectile dysfunction in a patient, consisting of a rigid disk, wherein the rigid disk is made of a mixture of materials, wherein the mixture of materials consists essentially of a filmogenic polymer, an effective dose of a therapeutic agent suitable for treating erectile dysfunction, and at least one additive selected from the group consisting of a stabilizer, a solubilizer, an enhancer and a plasticizer.

Rule 1.126 38. A delivery device for treatment of erectile dysfunction in a patient, consisting of a rigid disk, wherein the rigid disk is made of a mixture of materials, wherein the mixture of materials consists essentially of a filmogenic polymer, an effective dose of a therapeutic agent suitable for treating erectile dysfunction, and at least one additional therapeutic agent.

Rule 1.126 39. A method of treating erectile dysfunction, comprising:

selecting a device consisting of a rigid disk, wherein the rigid disk is made of a mixture of materials, wherein the mixture of materials consists essentially of a filmogenic polymer, an effective dose of at least one therapeutic agent suitable for treating erectile dysfunction and a plasticizer;

wetting a penile surface; and

placing the device in contact with the wetted penile surface delivering the at least one therapeutic agent to the penile surface over an effective period of time.